**United** Radiology Systems, Inc.
151 South Pfingsten Road, Unit T
Deerfield, Illinois 60015

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MAY 1 4 2004

# 510(k) SUMMARY
# FOR
# KMC-950 C-ARM MOBILE X-RAY UNIT

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Pat 807.87 (a) to (h).

## 1.0. Identification of submitter

United Radiology Systems, Inc
151 S. Pfingsten Road, Unit T
Deerfield, IL 60015

Establishment Registration No. : # 1424287
Corresponding official : John W. Lee / President

## 2.0. Identification of Product

Trade / Model Name : KMC-950, C-arm Mobile
Panel : X-Ray System
Classification : Class II

Product Code : Fluoroscopic, Image Intensified ( 90 JAA)

Regulation No. : 21 CFR 892. 1650/ Product code : 90 JAA, OWB, OXO

Manufacturer : COMED Medical Systems, Inc.
58 Hak-Dong, Chowol-Myun,
Kwangju-Shi, Kyunggi- Do
South Korea

## 3.0. Reason for 510 (k) PMN Submission

KMC-950, C-arm mobile is new X-ray mobile systems.

## 4.0. Product Description

The KMC-950 is a C-arm X-ray mobile systems consisting of a C-arm stand base and monitor trolley. The C-arm mobile stand holds the high-frequency X-Ray generator, X-ray tube assembly, X-ray controls, image intensifier and CCD camera.

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Monitor trolley supports the image display TV monitors, image processing and recording devices.

KMC-950 are providing a dynamic motion images on the TV monitor in such principles of lower dosage, better image quality and digital manipulation, workflow enhancement, operator and patient comfort and versatility.

A general radiographic stationary images are able to produce on x-ray film. Therefore a cassette holder is provided with the mobile system.

**5.0. Intended Use :**

The KMC-950 C-arm X-ray mobile system is used to meet the radiographic and fluoroscopic image & visualization required in surgical, orthopedic and emergency room operation.

The fluoroscopic mode of operation allows the attending physician to see the image directly on the TV monitor in real time without the need to develop individual films.

**6.0. Equivalent Devices :**

The KMC-950 C-arm X-ray mobile systems are substantially equivalent to a legally marketed predicate devices and 510(k) numbers with regard to safety and effectiveness as following list :

- GE OEC 9800 PLUS : K 021049
- Siemens, Siremobile ISO-C : K 973598
- Medison Acoma, MCA-6100 : K993896✓
- ELMSTech. IMPERIUM : K022114

**7.0. Performance Standards :**

The KMC-950 is designed in accordance with the national and international product safety and performance requirements established in the following standards :

- 21 CFR 1020.30-32 : Federal Performance Standard for Diagnostic X-ray Systems.
- IEC 60601-1-1 : Medical Electrical Equipment- Part 1. General Requirements for Safety 1 & 2
- IEC 60601-1-2 : Medical Electrical Equipment – Part 1.
  - General Requirements for Safety- 2
  - Collateral Standard / Electromagnetic Compatibility- Requirements & Test

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- IEC 60601-1-3 : Medical Electrical Equipment- Part 1
  - General Requirement for safety –3
  - Collateral Standard / General requirement For radiation protection in diagnostic x-ray equipment.
- IEC 60601-2-7 : Medical Electrical Equipment- Part 2, Particular Requirements for the safety of high voltage of diagnostic x-ray generators
- IEC 60601-2-28 Medical Electrical Equipment, X-ray tubes and X-ray Source Assemblies
- IEC 60601-2-32 Medical Electrical Equipment, Part 2 Particular Requirements for the Safety of associated devices of X-ray equipment .

Results of performance and compliance testing conducted at manufacturing facility and independent test organization on KMC-950 C-arm mobile systems, indicates conformance to all applicable performance standards promulgated by FDA for these systems.

## 8.0. Component & Material

Certifiable Component List

| General Description | Component / Model Designation |
|---|---|
| X-ray Controller | KMC-950-HFG-C |
| High Tension Transformer | KMC-950-HTT |
| Image Intensifier Tube | TH-9466 |
| X-ray Tube | KMC-950-RAD-99 |
| Collimator | KMC-950-CM-4MR |

## 9.0. Appendix & Attachment :

**A. Product Comparison List**

**B. Product Identification & Labels**

**C. PMN Truthful & Accurate Statement**

**D. Premarket Notification 510(k) Statement**

**E. Software Validation & Verification**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 22 2012

Mr. John W. Lee
President
United Radiology Systems, Inc.
151 South Pfingsten Road, unit T
DEERFIELD IL 60015

Re: K032761
Trade/Device Name: KMC-950 C-Arm Mobile System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO, and JAA
Dated: April 23, 2004
Received: April 27, 2004

Dear Mr. Lee:

This letter corrects our substantially equivalent letter of November 14, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

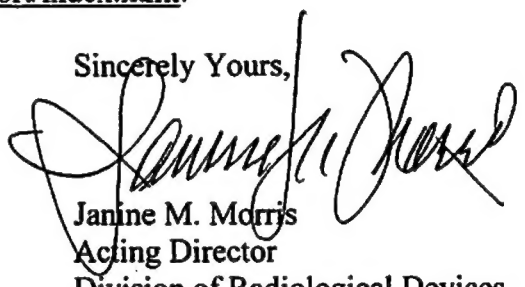
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## STATEMENT OF INTENDED USE

510 (k) Number ( If known) : ~~Not known~~ K032761
Device Name : KMC-950 C-arm Mobile System

INDICATIONS OF USE :

The KMC-950 is intended to provided fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography, orthopedic, neurological, abdominal, vascular, cardiac, critical care and emergency room procedures.

The system may be used for other RF imaging application at physician's discretion.

( Please do not write below this line – continue on the another page if needed )

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over- The – Counter – Use_____
( Per 21 CFR 801.109 ) ( Optional Format 1-2-9)

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032761